REMARKS

1. Examiner objected to claim 10 for being dependent from a cancelled claim. For examination purposes, Examiner has assumed claim 10 depended from claim 1.

2. Claim 10, depended from claim 9, which is currently withdrawn from consideration. Claim 10 has been amended to depend from claim 1, as presumed by Examiner.

Rejection under 35 USC 102(e) - Shahidi (US 6,167,296)

3. Examiner rejected claims 1-4, 20, 24 and 32 under 35 USC 102(e) as being anticipated by Shahidi (US 6,167,296).

4. Applicant respectfully disagrees with Examiner's assertion that claims 1-4, 20, 24 and 32 are anticipated by Shahidi. Applicant submits that it is not possible to use Shahidi in Sclemm's Canal as recited in the claims of the present application. And therefore Shahidi fails to discloses an apparatus as recited by Applicant. The reasons are primarily related to the small scale of Schlemm's canal, the deformability of the eye as compared to neurosurgical or orthopedic applications involving bone, and the need to advance a microcannula into a tissue passageway such as Schlemm's Canal. If it were to navigate through Schlemm's Canal, it would damage the Canal rendering it impossible to advance the microsurgical device into the Canal as claimed by Applicant.

5. In Shahidi:

> Shahidi "provides an improved system and method for displaying 3D images of anatomical structures in real time during surgery to enable the surgeon to navigate through these structures during the performance of surgical procedures. This system is also useful in planning of surgical procedures. The system includes a computer with a display and input devices such as a keyboard and mouse. The system includes a position tracking system that is connected both to the computer and also to the surgical probes or other instruments that are used by the surgeon. The position tracking system provides continual real time data to the computer indicating the location and orientation of the surgical instrument in use. The

computer further includes a memory containing patient data produced by imaging scans, such as CT or MRI scans, from which 2-dimensional and 3-dimensional images of the anatomical structure may be generated. Means are provided for registration of these images with respect to the patient." (Column 3, lines 22-39)

"In addition, for probes or instruments being used that are capable themselves of generating images, such as ultrasound probes, endoscopes, or surgical microscopes, the system provides means for integrating these images with those generated from the scan data. The software enables the user to overlay the 'actual images' generated by these instruments with the 'virtual images' generated from the scan data." (Column 4, lines 6-13)

6. As previously stated, in Shahidi, the use of stored patient image data to provide surgical guidance in real time relies upon the stored image data remaining accurate during surgery. For surgical targets involving hard tissues such as bone and cartilage, this method has obvious applicability, for example in neurosurgery or orthopedic surgery. However, means for registration of images as required by Shahidi are possible only when involving hard tissues by using fiducials (Column 5, lines 33-37) affixed to bone or cartilage.

The eye is a relatively soft structure, whose size and shape relates to the intraocular pressure and forces being applied directly during surgery. Whereas, with the large deformability of the tissues of the eye relative to the dimensions of the tissue target of the present invention, Schlemm's Canal, the Shahidi image registration method would seem to be of no practical use, since the method of Shahidi would not provide data reliable enough for use in guiding a surgical instrument to Schlemm's Canal of the eye.

Further, routine eye surgery clearly demonstrates that the insertion of any surgical instrument into the sclera of an eye as described by our application results in a large deformation of the eye relative to the size of Schlemm's canal. The creation of holes into the eye as Shahidi describes for the skull (Figure 11A) would cause loss of intraocular pressure and deflation of the eye, again rendering the pre-operative imaging data highly inaccurate.

In summary, variations in the patient's intraocular pressure, the use of a protective paracentesis to remove intraocular pressure during eye surgery, and the force applied to the

eye by the imaging means or the microsurgical device can change the size and shape of the anterior segment angle containing Schlemm's Canal by several millimeters. Since Schlemm's Canal is a tissue structure of approximately 150 microns in diameter, such lack of accuracy of potentially thousands of microns from the stored image data would be ineffective in guiding a microcannula to Schlemm's Canal by Shahidi.

7. The microcannula of Applicant's claimed invention is sized to access Schlemm's Canal. Such small dimensions limit the use of the microcannula to generate images to integrate with stored scan data as described in Shahidi. Images from a 150 micron diameter cannula would be limited in depth and breadth due to the restricted size for the imaging components, such as aperture size. While viewing reconstructed images from the perspective of a surgical instrument may be useful for avoiding certain tissues in the path of the surgical instrument, it is of limited utility in guiding a small device to a small target. If the view from the instrument is off target, the image provided by imaging means in the instrument or microcannula would simply be of the off target tissues. The scope of imaging from a small microcannula is too restricted to allow it to readily find the correct target, unless it happens by chance to be in its imaging path. The best method to guide a surgical instrument to a tissue target is to image the tissue target in reference to the instrument from a position able to view both the target and the instrument, not from the point of view of the surgical instrument.

8. Furthermore, Shahidi only allows guidance of the trajectory of the surgical instrument toward the target tissues and the imaging of tissue structures in the path of the surgical instrument. In the presently claimed invention, it is not sufficient to simply guide the tip of the surgical instrument to the target tissues, instead it is desired to guide the instrument into and along the lumen of Schlemm's Canal. Applicant's claimed invention is described to advance a microsurgical device **into** a tissue space identified with Schelmm's Canal. If we were to navigate **through** Schlemm's Canal, it would damage the Canal rendering it impossible to advance the microsurgical device into the Canal. There is no apparent way Shahidi could be used to guide a surgical instrument **into** a deformable soft tissue structure such as Schlemm's Canal.

9. The examiner further cited Figures 1 through 8 from Shahidi. The fact that Shadhidi describes a computer program integrated with the locating means does not assure that the invention of Shadidi has a locating means that is capable of being used to non-invasively locate Schlemm's Canal in an eye that is coupled with a microsurgical device that is capable of being advanced into a tissue space identified with Schlemm's canal, as claimed by Applicant. The reason is simply that the computer program does not have the appropriate data regardless of the sophistication of said computer program. For example, referring to the Figure 1 cited by the examiner, the "fiducial markers 113, 114 are attached to the head to enable registration of images generated previously obtained scan data according to techniques familiar to persons of ordinary skill in the relevant art." It is clear that fiducials attached to the skull as shown in Figure 1 of Shahidi would not aid in registering of images of Schlemm's Canal since the eye can move independently of the skull.

   Applicant's invention does not use fiducials or previously obtained images or scan data for real time image registration. As stated above, these devices are inadequate to provide locating means that is capable of being used to non-invasively locate Schlemm's Canal in an eye that is coupled with a microsurgical device that is capable of being advanced into a tissue space identified with Schlemm's canal. It is not effective to attach fiducials to the eye since the deformation of soft tissues such as the eye would render any such location reference inaccurate, especially to locate a 20 to 150 micron diameter tissue structure such as Schlemm's Canal.

10. Examiner also cites that the locating means of Shahidi has a device that is capable of being used for ultrasound examination of the sclera (col 7, lines 37-41) or an ultrasound imaging system. Examiner also refers to Figure 4 of Shahidi. Applicant believes that Examiner has misinterpreted Shahidi. The cited portion of the Shahidi patent refers to "The surgical instrument 109 may include an ultrasound transducer located at the tip 115, which itself scans and detects ultrasound imaging data when placed in contact with the patient's head". And later, "These intra-op images are fused 406 with the pre-op image generated by the pre-op

protocol 311, and the composite images are further displayed." (column 7, lines 61-64). Figure 4 of Shahidi as cited by the examiner, illustrates the fusion of acquired ultrasound data with pre-operative images, which appears to be required by the data flow arrows in the figure.

Applicant's invention relies upon the real time images generated by an imaging system to locate Schlemm's Canal in an eye, and a microsurgical device coupled with the locating means so as to advance the microsurgical device into a tissue space identified with Schlemm's Canal.

Again, in Shahidi, the use of stored patient image data to provide surgical guidance in real time relies upon the stored image data remaining accurate during surgery. However, the eye is a relatively soft structure, whose size and shape relates to the intraocular pressure and forces being applied directly during surgery. Variations in the patient's intraocular pressure, the use of a protective paracentesis to remove intraocular pressure during eye surgery, and the force applied to the eye by the imaging means or the microsurgical device can change the size and shape of the anterior segment angle containing Schlemm's Canal by several millimeters. Since Schlemm's Canal is a tissue structure of approximately 150 microns in diameter, such lack of accuracy of potentially thousands of microns from the stored image data would be ineffective in guiding a microcannula to Schlemm's Canal by the method of Shahidi.

11. Examiner newly cited (Col 11, line 57 to Col. 12, line 21) of Shahidi in her 'Response to Arguments.' Applicant has reviewed the cited sections of the reference. In reference to Display 1404, the actual image seen by the endoscope, we note that it is not possible to locate and guide the device to a tissue target unless the target is by chance already located in front of the endoscope. Display 1405, 1406, 1407, 1408 and 1409 are described as virtual images created by computation of the pre-operative volumetric scan data referenced to the position of the endoscope within the skull The method described by Shahidi relies upon the use of such pre-operative volumetric scan data, as referenced in Figures 3, 4, 5, 6, 7, 8, 14, and 15. As previously stated, while suitable for use in areas of fixed tissue geometry relative to hard tissues such as the skull, the method of Shahidi is not suitable for use where introduction of

the surgical probe or instrument distorts the shape of the tissue thereby rendering the pre-operative image data inaccurate. This is especially true when the size of distortion of the tissue is greater than the size of the tissue target such as the Schlemm's canal of the eye. In addition, the use of fiducial markers for image registration as shown in Figure 1 of Shahidi would not be effective for the registration of images for the eye due to the independent movement of the eye in reference to the skull. Fiducials placed on the eye would be also be inaccurate due to the large deformation of the eye during device introduction or surgical manipulation, including the insertion of a surgical probe or instrument into scleral tissues to access Schlemm's canal.

12. Regarding claim 24, the examiner refers to Figure 1 of Shahidi. We disagree that Figure 1 discloses that the locating means 110, 111 and the surgical instrument 109 are disposed within a unitary body. The relative position of the surgical instrument of Shahidi is only known by communicating with the position tracking system of Shahidi. Therefore the locating means of Shahidi comprises the position tracking system including the fiducials 113, 114, the imaging means, and the stored pre-op imaging data. It is evident from Figure 1 that the locating means and surgical instrument of Shahidi are not disposed within a unitary body.

13. Regarding claim 32, the examiner states that the surgical instrument 109 is coupled coaxially with the locating means 115 (ultrasound transducer). If this rejection is reiterated, Applicant respectfully request clarification of where this feature is found in Shahidi and how it relates to Applicant's claim.

14. In conclusion, Shahidi does not disclose a device that could be used to locate and advance a microsurgical device into Schlemm's Canal as recited in claims 1-4, 20, 24 and 32. Therefore, Applicant respectfully requests that the rejection under 102(e) be withdrawn.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Thomas III et al (4911170)

15. Examiner rejected claim 6 and 7 under 35 USC 103(a) as being unpatentable over Shahidi in view of Thomas III et al (4911170).

16. Thomas discloses a catheter with a broadband 25 to 50 MHz spherically focused ultrasonic transducer placed on the tip of a catheter such that ultrasonic images of arteries and plaque are produced by introducing the catheter into arteries of patients. Also Thomas describes:

> "The catheter tip is approximately hemispherical and the high frequency spherically focused transducer is mounted on the tip to transmit ultrasound approximately perpendicular to the longitudinal axis of the catheter so as to be incident on a wall of the artery and detect ultrasound backscattered from the wall and any plaque in the artery." (column 2, lines 34-40).

As described, the invention of Thomas is a typical side-imaging catheter used in cardiology. It is unclear how a side imaging catheter would be effective as the surgical instrument of Shahidi, as it would not provide forward facing imaging (the cone-shaped volume in the region of interest described by Shahidi) nor is the plane of the scan sector collinear with the longitudinal axis of the surgical instrument 109 as described by Shahidi (column 7, lines 37-52), in fact it is in the perpendicular direction. Also it should be noted that since the transducer of Thomas is not a phased focusing array as described by Shahidi (column 7, line 43-48) or rotated along the scan plane axis, volumetric scan data would not be generated, and would not produce 3D imaging information as required by Shahidi. As cited by the examiner in the first paragraph of the Summary of Invention section of Shahidi:

> "The present invention provides an improved system and method for displaying 3D images of anatomical structures in real time during surgery to enable the surgeon to navigate through these structures during the performance of surgical procedures. This system is also useful in planning of surgical procedures". (column 3, lines 21-26).

Therefore, it would be counter to the purpose of Shahidi to use the ultrasonic transducer of Thomas if forward directed images could not be acquired and 3D images would not be possible. As such, Applicant submits that the combination Shahidi and Thomas does not

disclose or suggest an ultrasound device for examination of the sclera within the 10 and 40 MHz ranges as recited in claims 6 and 7. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Bernstein (6,132,699)

17. Examiner rejected claim 8 under 35 USC 103(a) as being unpatentable over Shahidi in view of Bernstein (6,132,699).

18. Applicant respectfully disagrees with Examiner's rejection. Bernstein et al. describes methods

> "for the synthesis of polymeric delivery systems consisting of synthetic polymeric microparticles which contain fluorinated gases, especially perfluorocarbons. The microparticles are useful in a variety of diagnostic ultrasound imaging applications, particularly in ultrasound procedures such as blood vessel imaging and echocardiography. The incorporation of a fluorinated gas significantly increases the echogenicity as compared with the same synthetic polymeric microparticles incorporating air." (Column 5, lines 9-18)

While Bernstein et al. describes the use of contrast agents for ultrasound imaging, it does not describe the use of contrast agents for image guided surgery or suggest any rationale for use in such applications. Since the invention of Shahidi utilizes a position tracking system in comparison to stored pre-op images to locate target tissues relative to a surgical instrument, it is unclear how the use of a contrast agent such as described by Berstein would disclose or make obvious the missing limitations from Shahidi to function with soft, deformable tissues such as the eye.

19. Therefore, Applicant submits that the combination Shahidi and Bernstein et al. does not disclose or suggest the features recited in claim 8. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of LeBlanc et al. (5,989,189)

20. Examiner rejected claim 10 under 35 USC 103(a) as being unpatentable over Shahidi in view of LeBlanc et al. (5,989,189).

21. Applicant respectfully disagrees with Examiner's rejection. LeBlanc et al. describes

> "a system for producing visual representations of eye structures that includes an ultrasound transducer, a processor, and a display device. The ultrasonic transducer transmits ultrasound signals into eye structures, receives ultrasound signals reflected by the eye structures, and sends electronic signals representative of the received ultrasound signals to the processor. The processor translates the electronic signals into image data representing a non-background portion of an image for display by the display device by correlating each value of a parameter of the electronic signals (e.g. each value of echo signal intensity) with one of a plurality of multichromatic color hues in accordance with a continuous gradation of the multichromatic color hues that forms the entirety of the non-background portion of the image." (Column 2, lines 32-46)

22. The use of ultrasound to image the larger structures of the eye are well known in ophthalmic imaging. The eye structures described by LeBlanc et al. such as the cornea, retina, sclera, are large structures with dimensions on the order of thousands of microns. Schlemm's Canal of the eye is a small vein-like structure approximately 150 micron in diameter. LeBlanc describes an ultrasound system in which the display image comprises ultrasound signals that are color mapped with different characteristics of the received ultrasound signals, such as echo intensity or phase. LeBlanc does not describe using such information for locating or identifying tissues, but rather how to color map to allow the viewer to improve image presentation and to better discriminate eye structures. LeBlanc et al. would be incapable of the resolution necessary to locate a small tissue spaces such as Schlemm's Canal as would be necessary to fulfill the recited limitations of claim 10. The LeBlanc patent does not describe, demonstrate or suggest locating Schlemm's Canal, the use of imaging to direct a microcannula or any surgical instrument or displaying a signal or imaging information to direct the transducer location.

23. Therefore, it would not disclose or make obvious the missing limitations above. Therefore a combination of LeBlanc et al. and Shahidi would still not disclose or suggest the device recited in claim 10.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Schachar (6,146,366)

24. Examiner rejected claim 18 under 35 USC 103(a) as being unpatentable over Shahidi in view of Schachar (6,146,366).

25. Applicant respectfully disagrees with Examiner's rejection. Schachar describes a device to be implanted into scleral tissues in the posterior region of the eye and alter the shape of the eye. Shahidi is designed to act as an invasive surgical instrument in conjunction with stored pre-operative images of presumably unaltered shape. So, it is unclear how Schachar could even be used with Sahidi, since Sahidi utilizes stored image data for image guidance and Schachar is meant to alter the shape of the eye. The altered shape of the eye would make the stored image data of Sahidi inaccurate and therefore of little use.

26. Furthermore, Schacher teaches away from Applicant's claimed device. Applicant's device is designed to minimize trauma to surrounding tissue. Further, the alteration of the shape of the eye would apply undesired force and distortion during the guidance of the microcannula of Applicant's claimed invention.

27. Therefore, Applicant submits that it would be counterproductive to combine the devices of Scachar and Sahidi. Further, even if the references were combined, the combination does not disclose or suggest the features recited in claim 18. Applicant respectfully requests that this rejection be withdrawn.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Steen et al. (5,984,904)

28. Examiner rejected claims 19, 27-29, 31 and 46 under 35 USC 103(a) as being unpatentable over Shahidi in view of Steen et al. (5,984,904).

29. Applicant respectfully disagrees with Examiner's rejection. Steen et al. describes

> "a sleeve for use with a surgical instrument having a slender cutting tip for removing the natural lens from an eye. The surgical sleeve includes a contoured interior surface which provides superior performance in reducing the frictional contact between the sleeve tip, and maximizes the effect of the fluid flow about the tip." (Column 1, lines 64-67, Column 2, lines 1-3)

30. Steen et al. does not described or suggest a microcannula designed to penetrate through the tissues of the sclera, to enter the cannalicular space and to allow advancement into Schlemm's Canal with minimal risk of trauma to adjacent tissues.

Since, the addition of the features of Steen et al. would not disclose or suggest the limitations absent in Shahidi, no combination of these reference could disclosure or suggest Applicant's claimed configuration. Therefore, Applicant submits claims 19, 27-29, 31 and 46 are novel and nonobvious over the combination of Shahidi and Steen et al. Applicant respectfully requests withdrawal of this rejection.

31. Further, Steen in describes "Surgical procedures which require only a small incision to be made in the eye have been developed for removing the natural lens. In accordance with these procedures, a slender cutting tip of a surgical instrument is inserted through the incision to engage the natural lens. The cutting tip is typically subjected to ultrasonic vibrations to emulsify the lens (e.g., phacoemulsification). The emulsified portions of the lens are then aspirated from the eye through a central bore in the tip. A silicone sleeve surrounds the tip to define an annular conduit for the passage of fluid to cool the tip and irrigate the eye." It is important to note that the device of Steen operates by ultrasonic vibrations to emulsify the natural lens. Therefore, if the cutting tip of Steen were added to Shahidi, the ultrasonic

vibrations of the cutting tip would interfere with the ultrasound imaging signals.

32. Therefore, Applicant submits that it would be counterproductive to combine these references. And even if the references were combined, the combined device would not create Applicant's claimed invention. Therefore, Applicant submits that claims 27, 29 and 46 are novel and nonobvious over Shahidi and Steen. Allowance of these claims is respectfully requested.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296)

33. Examiner rejected claim 21 under 35 USC 103(a) as being unpatentable over Shahidi.

34. As mentioned above with regards to claims 1-4, 20, 24 and 32, there are design features of Shahidi, which would preclude its use in Schlemm's Canal. Therefore, there would be no reason to create the device of Shahidi in a size to fit within Schlemm's Canal. And even if Shahidi were created in a size capable of entry into Schlemm's Canal, it would not be suitable for such a use. Altering the size of Shahidi would not solve the problems with the inaccuracy of the stored data with respect to a soft tissue structure, image registration and device guidance into the structure, as discussed in further detail above.

35. Therefore, Applicant submits that claim 21 is novel and nonobvious over Shahidi and respectfully requests withdrawal of this rejection.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Imling et al. (6,203,499)

36. Examiner rejected claims 22 and 23 under 35 USC 103(a) as being unpatentable over Shahidi in view of Imling et al. (6,203,499).

37. Applicant respectfully disagrees with Examiner's rejection. Imling et al. describes:

> "a one piece needle guide is provided that consistently guides a needle into the insertion point of the body being examined such that the needle always enters the

scan plane. The needle guide of the present invention also provides the user with the ability to freely maneuver the needle at multiple angles before and after insertion of the needle into the body being examined, while keeping the needle within the scan plane such that it is detected. The needle guide of the present invention is easy to clean, easy to operate, can be used with a wide range of needle sizes, and allows for the quick and easy release of the needle from the needle guide if required." (Column 3, lines 41-52)

Imling describes a needle guide that positions a biopsy needle in the scan plane of an ultrasonic imaging probe and also provides the ability to maneuver the needle at multiple angles before and after insertion of the needle into the body. The angular variation is within the scan plane of the probe.

Applicant's claim 22 recites a:

"microcannula coupled to the locating means at an angle between 0 and 30 degrees from the plane of Schlemm's Canal in the eye."

Applicant is not just trying to get a needle tip to a general tissue area under imaging guidance, for example to sample tissue of a lesion for biopsy as in Imling. Applicant's invention relates to introducing a surgical device into the vein-like tissue space of Schlemm's canal and advancing the device along the canal to allow for the therapeutic injection of materials, inflatable balloons and implants into Schlemm's Canal. For example when injecting into a vein with a needle and syringe, a physician does not simply place the tip of the needle into the blood vessel at an acute angle. The needle is placed somewhat in alignment with the vessel and advanced for at least a short distance within the vein so the injectate may be induced to flow into the vein. This requires a near parallel approach to the canal long axis so that the surgical device does not simply transect or go through the canal.

38. Further, the invention of Imling et al. does not appear suited for guidance of a needle sized to access Schlemm's Canal. For example, "Needle guides are generally sized for one needle size, ranging from a large needle at 16 gauge to smaller needles at 22 gauge." (Column 3, lines 21-23) These needles sizes translate to 807 microns (22 gauge) and 1,625 microns outer

diameter. It is difficult to envision placing these needles into an approximately 150 micron tissue space such as Schlemm's Canal. Also, the invention is described as "in any selected angle, needle 22 may freely move within slot 44 while it is inserted in the body being examined." (Column 5, lines 19-21) This indicates a lack of precision to place a needle or microcannula into a space as small as Schlemm's Canal.

39. Also, it is unclear how a needle guide as described by Imling would be combined with Shahidi. Shahidi describes a surgical probe or instrument coupled to a position tracking and display system, so that "a surgical probe or instrument held by the surgeon is directed toward the tissues of interest" (column 5, lines 37-38, Figure 1). It is unclear where the needle guide of Imling which is described to be attached to an ultrasonic imaging probe so that the needle would be in the imaging scan plane, would be incorporated into the hand held surgical probe or instrument of Shahidi since the imaging described by Shahidi is forward directed from the tip of the surgical probe or instrument. In other words, if the Shahidi invention is providing the scan plane from the probe or instrument tip, the surgical probe or instrument of Shahidi is never in the scan plane as described by Imling. Also, it is unclear why a needle guide as described by Imling would be combined with Shahidi since it is the intent of Shahidi to provide superior utility as compared to the use of "guides for channeling the surgical tool along a desired trajectory" (column 1, .line 65 to column 2 line 6) such as described by Imling.

40. Therefore, since neither of the cited prior art of Imling or Shahidi, shown or suggested a microcannula being advanced into Schlemm's Canal or any vein-like structure, nor does the needle need to be advanced within a tissue structure as claimed in claims 22 and 23, Applicant submits that a combination of Shahidi and Imling does not suggest or create the invention claimed in claim 22. Allowance of claim 22 and 23 is respectfully requested.

<u>Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Simon (4,883,053)</u>

41. Examiner rejected claim 25 under 35 USC 103(a) as being unpatentable over Shahidi in view of Simon (4,883,053).

42. Simon describes a biopsy needle guide or "angulator". Simon also describes a pair of clips located on a secondary member of the device shown to aid in retention of a biopsy needle in Figure 5. As discussed above, Shahidi fails to describe or suggest the features recited in claim 20, from which claim 25 depends. Simon also does not include these features.

43. Therefore, since neither of the cited prior art of Simon or Shahidi, shown or suggested a microcannula being advanced into Schlemm's Canal or any vein-like structure, nor does the needle need to be advanced within a tissue structure as claimed in claims 25, Applicant submits that a combination of Shahidi and Simon does not suggest or create the claimed. Allowance of claim 25 is respectfully requested.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Mohr, Jr. et al. (5,921,954)

44. Examiner rejected claim 26 under 35 USC 103(a) as being unpatentable over Shahidi in view of Mohr, Jr. et al. (5,921,954).

45. Mohr discloses a curved catheter. Mohr describes preferred embodiments for the catheter tube to comprise inert and non-conductive substances such as woven Dacron, Kevlar, nylon, or combinations thereof, materials of low flexural rigidity. Catheters are typically considered to be flexible, tubular structures that allow placement into curved and often tortuous biological spaces such as blood vessels, in comparison to cannulas which are rigid tubular structures. A flexible construct such as the catheters of Mohr would fail to perform satisfactorily in combination with Shahidi since a deformation of the distal end of the catheter would make the position of the tip inaccurate from the position sensors in the handle

Further, even if Mohr was combined with Shahidi, it would still fail to disclose or suggested

the features of 26, which depends from claim 20. The curved catheter of Mohr does not show or suggest the features Shahidi lacks.

46. Therefore, since neither of the cited prior art of Shahidi or Mohr, Jr. et al., shown or suggested a microcannula being advanced into Schlemm's Canal as claimed in claims 26, Applicant submits that a combination of Shahidi and Mohr, Jr. et al. does not suggest or create the claimed. Allowance of claim 26 is respectfully requested.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Lynch et al. (6,524,275)

47. Examiner rejected claims 32-34, 38 and 45 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lynch et al. (6,524,275).

48. Applicant respectfully disagrees with Examiner's rejection. While Lynch et al. describes the use of an inflatable device placed within Schlemm's canal, it does not describe means for placing the device within the Canal by minimally invasive means. "The surgical procedure necessary to insert the device requires an approach through a fornix-based conjunctival flap." (Column 7, lines 53-55.) It is unclear how the use of Lynch et al. would overcome the intrinsic limitation of Shahidi to function with soft, deformable tissues, as discussed above.

In Applicant's invention, we describe injection of materials, inflatable balloons and implants into Schlemm's canal. This would be very difficult, if the surgical device or microcannula is not placed advanced into the canal as recited in claim 32, 38 and 45. Shahidi does not describe means to access and advance a microcannula into a tissue space such as Schlemm's Canal, and Lynch et al. does not provide any suggestion to include this feature. Therefore a combination of these references would not create or suggest a device as recited in claim 32.

49. Therefore, Applicant submits that claims 32-34, 38 and 45 are novel and nonobvious over the combination of Shahidi and Lynch et al. and respectfully requests that this rejection be withdrawn.

Rejection under 35 USC 103(a) - Shahidi (US 6,167,296) in view of Lafont et al. (5,957,975)

50. Examiner rejected claims 39 and 42 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lafont et al. (5,957,975).

51. Applicant respectfully disagrees with Examiner's rejection. Lafont et al. describes the use of biodegradable vascular stents. However, the ultra structure and anatomy of Schlemm's Canal differs significantly from arteries, lacking a tunica media and tunica adventitia associated with arterial remodeling. Therefore, it would not be obvious to one of ordinary skill in the art that Schlemm's Canal of the eye could undergo arterial remodeling, the biological mechanism involved of the invention described in Lafont et al.

    As discussed above, Applicant's application describes injection of materials, inflatable balloons and implants into Schlemm's canal, including an expandable stent and an expandable stent comprised of a biodegradable material through minimally invasive means. This would be very difficult if the surgical device or microcannula is not placed within the canal and advanced within the canal for at least a short distance.

52. Since, the addition of the features of Lafont would not include the limitations missing Shahidi to function with soft, deformable tissues, as argued above with respect to claim 38, from which claims 39 and 42 depend, Applicant submits claims 39 and 42 are novel and nonobvious over the combination of Shahidi and Lafont. Applicant respectfully requests that this rejection be withdrawn.

53. In summary, the prior art cited does not describe means to introduce and advance a surgical device or microcannula into a tissue space (cannulation) such as Schlemm's Canal, to advance the microcannula at high precision or means to couple advancement of the surgical tool under control by the imaging system.

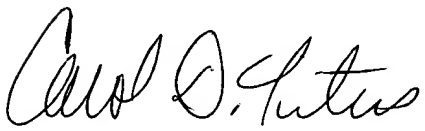
54. Applicant has also included new claims 64-77 to further distinguish over the prior art. Applicant submits that these claims are also novel and nonobvious over the prior art.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,



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